

Original citation:

Khatri, Chetan, Ahmed, Imran, Parsons, Helen, Smith, Nicholas A., Lawrence , Tom, Modi, Chetan, Drew, Steve, Bhabra, Gev, Parsons, Nicholas R., Underwood, Martin and Metcalfe, Andrew (2018) The Natural History of Full-Thickness Rotator Cuff Tears in Randomized Controlled Trials: A Systematic Review and Meta-analysis. American Journal of Sports Medicine . doi:10.1177/0363546518780694

Permanent WRAP URL:

<http://wrap.warwick.ac.uk/104280>

Copyright and reuse:

The Warwick Research Archive Portal (WRAP) makes this work by researchers of the University of Warwick available open access under the following conditions. Copyright © and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable the material made available in WRAP has been checked for eligibility before being made available.

Copies of full items can be used for personal research or study, educational, or not-for profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

Publisher's statement:

Citation: Khatri, Chetan, Ahmed, Imran, Parsons, Helen, Smith, Nicholas A., Lawrence , Tom, Modi, Chetan, Drew, Steve, Bhabra, Gev, Parsons, Nicholas R., Underwood, Martin and Metcalfe, Andrew (2018) The Natural History of Full-Thickness Rotator Cuff Tears in Randomized Controlled Trials: A Systematic Review and Meta-analysis. American Journal of Sports Medicine . doi:10.1177/0363546518780694

Copyright © The Author(s) 2018. Reprinted by permission of SAGE Publications.

Published version: <https://doi.org/10.1177/0363546518780694>

A note on versions:

The version presented here may differ from the published version or, version of record, if you wish to cite this item you are advised to consult the publisher's version. Please see the 'permanent WRAP url' above for details on accessing the published version and note that access may require a subscription.

For more information, please contact the WRAP Team at: wrap@warwick.ac.uk

1 **The Natural History of Full Thickness Rotator Cuff Tears in**
2 **Randomised Controlled Trials: A Systematic Review & Meta-**
3 **Analysis of Operative and Nonoperative Treatments**
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30

31 **Declarations**
32

33 Running title:	Natural History of Full Thickness Rotator Cuff Tears
34 Funding:	No funding was received for the completion of this 35 project.
36 Competing interests:	We declare that we have no conflicts of interest in the 37 authorship or the publication of this contribution
38 Acknowledgments:	Nil
39 Ethical Approval:	There was no ethics needed for this paper
40 Data sharing statement:	All data is presented in this paper. There is no 41 additional unpublished data 42

Abstract

Background: Rotator cuff tears are the commonest tendon injury in the adult population, resulting in substantial morbidity. The optimum management for these patients is not known.

Purpose: To assess the overall treatment response to all interventions in full-thickness rotator cuff tears in patients enrolled in randomised clinical trials.

Study Design: Systematic review and meta-analysis.

Methods: Randomised controlled trials (RCTs) were identified from a systematic search of Medline, Embase and CINAHL databases. Patients aged 18 or over with full-thickness rotator cuff tear. The primary outcome measure was change of Constant shoulder score from baseline at 52 weeks. A meta-analysis to assess treatment response was calculated using the standardised mean change in scores.

Results: We included 57 RCTs. The pooled standardised mean change, compared to baseline was: 1.42 (95% CI 0.80-2.04) at 3 months, 2.73 (95% CI 1.06-4.40) at 6 months and 3.18 (95% CI 1.64-4.71) at 12 months. Graphical plots of treatment response demonstrate a sustained improvement in outcomes in both non-operative trial arms and all operative sub-group arms.

Conclusions: Patients with full-thickness rotator cuff tears demonstrated a consistent pattern of improvement in Constant score with both conservative and operative care. The natural history of patients with rotator cuff tears included in RCTs is to improve over time, whether treated operatively or non-operatively.

71 What is known about the subject: Rotator cuff tears represent the commonest tendon
72 injury in the adult population, however the optimum management of these patients is
73 not known. In other chronic musculoskeletal conditions, it has been shown that there
74 is improvement in clinical outcome measures with all treatments over time. However,
75 it is not known if this is also true for rotator cuff tears.

76

77 What this study adds to existing knowledge: This review found there is consistent
78 improvement in Constant score, irrespective of intervention given whether it is
79 operative, or non-operative treatments. Patient outcomes at 12 months are highly
80 predictive of outcomes at 24 months, suggesting that 12-month should be used as a
81 primary outcome time point for future randomised controlled trials in full-thickness
82 rotator cuff tears.

MAIN TEXT

Introduction

Rotator cuff tears are the commonest tendon injury in the adult population, affecting approximately 30% of the population above the age of 60⁸². The prevalence increases with age. Risk factors for development include male gender, employment consisting of manual labour and previous trauma⁹⁶. Whilst many tears are asymptomatic, up to 35% of patients will then progress to develop pain and inability to perform activities of daily living^{70,95}. For patients with full-thickness rotator cuff tears there is debate about the optimum management, including the use of different operative techniques, operative adjuncts, and non-operative management^{25,56}. Nevertheless, there has been a trend to provide more surgical treatments for these injuries. The number of rotator cuff repairs performed in the UK increased by 238% over 14 years to 2009²⁷.

Over recent years there has been a substantial growth in the number of randomised controlled trials and systematic reviews of shoulder treatments^{38,40,41,66}. However, most studies show, at best, a modest additional improvement in patient reported outcomes over time, with no clear superiority of one treatment modality over the other^{38,40,41,66}.

In other chronic, painful conditions, it has been noted that outcomes improve over time in patients in randomised trials, regardless of their treatment^{3,4,90}. This may be due to the natural history of chronic musculoskeletal conditions, regression to the mean or other unrecognised mechanisms. As a result, it presents a challenge for the interpretation of outcomes in studies of patients with rotator cuff tears. Randomised trials are a good source of information on the natural history of a condition because

they have well defined entry criteria, are prospective by definition, and typically have well defined follow-up time points. In addition, the natural history of patients with rotator cuff pathologies in randomised controlled trials needs to be better understood to improve the planning and conduct of further trials in this area.

Aims: To assess the outcomes and trajectories over time amongst patients with full-thickness rotator cuff tears in randomised clinical trials.

Methods

This study was reported in accordance with the PRISMA statement for reporting systematic reviews. The systematic review protocol was pre-defined and can be found at <http://www.crd.york.ac.uk/PROSPERO> (CRD42016047715).

Inclusion Criteria

Inclusion criteria were: (i) full text, randomised controlled trials in English language, (ii) any humans of any age with isolated full thickness rotator cuff tears, (iii) studies comparing both operative and non-operative interventions and (iv) reporting clinical outcome measures chosen for this review were included.

Exclusion Criteria

Exclusion criteria were: (i) non-randomised studies, (ii) studies reporting biomechanical and radiological outcomes, (iii) studies not reporting clinical outcomes selected for this review and (iv) abstract publication only.

Studies including patients with partial-thickness tears or examining treatments for shoulder disorders other than full-thickness tears were also excluded.

Up to three attempts were made to contact the corresponding author for additional information if; (i) further information was required about study design to confirm inclusion, (ii) there were missing data for unreported or partially unreported outcomes or (iii) outcomes were for the full-thickness sub-population where the study population was mixed (full thickness and other pathologies).

Outcome measures

The primary outcome measure was the Constant shoulder score²⁰ at 52 weeks. The Constant score is the most widely used shoulder evaluation score in Europe⁵¹ and has been described as the most efficient outcome measure for patients with rotator cuff tears⁶¹. It is a composite score measuring a combination of physical examination and subjective assessments from the patient.

The secondary outcome measures included: (i) the American Shoulder and Elbow Score (ASES)⁸³ at all time points, (ii) the University California-Los Angeles (UCLA)² score at all time points, (iii) the Disabilities of the Arm, Shoulder and Hand (DASH)³⁹ and (iv) Constant score (including modifications of the Constant score)²⁰ at all time points.

Search Strategy and quality assessment

We searched Medline, Embase, The Cochrane central register of controlled trials and CINAHL databases from inception to 14th September 2016 and imported citations into EndNote X7 (New York, USA) reference management software. A full search strategy can be found in the supplementary material. Following removal of duplicates, citations were screened using title and abstract with the inclusion criteria described above applied. To reduce the risk of publication bias, if multiple studies reported the same, or an overlapping population, only the study with the longest follow up was included. For those studies that potentially met eligibility criteria, full texts were obtained. Two authors (CK & IA) independently assessed each paper, with any discrepancies being resolved with discussion with the senior authors (NS & AM).

We did a qualitative risk of bias assessment using Cochrane guidelines ³⁷. Where the main paper did not include sufficient information to complete risk of bias assessment any published protocols were also examined.

Statistical analysis

We extracted outcome data from each study according to follow up time period. As there was often a wide heterogeneity in follow up time points, the exact time point was recorded, even if different for study arms. As performed in a similar meta-analysis by Artus et al. ³, we developed a data analysis plan, including a descriptive analysis, assessment of the variation of size of response and finally the overall pattern of response prior to data extraction.

Extracting data

We extracted the number of patients in each arm, the intervention type for each arm, which was defined as repair, acromioplasty alone or conservative. In addition, the mean and standard deviation (SD) of Constant score (standard and modified), gender, dominant hand and the time point assessed were extracted for each study. If a study did not report one of these statistics, then estimates of missing values were calculated from other reported values, such as the test statistic or p-value using standard methods as described in the Cochrane Handbook ³⁴. Where data in studies was not represented in numerical format, data were extracted from graphs by two authors (CK & IA) to improve accuracy of data.

Assessing the general response of treatment

Outcome scores were graphically plotted against time using Microsoft Excel (Microsoft Excel for Mac 2011, Washington, USA) to describe change from baseline to all follow up points reported in all treatment arms from included studies. Data were explored visually for a descriptive analysis of response. As a visual response trend was required, studies using modified versions of Constant score were included.

Assessing variation of size of response

To determine variation in size of response we analysed the change in outcome score by calculating the bias-corrected standardised mean change (SMC) at three, six, 12 and 24 months). This technique is used frequently when studies report efficacy in terms of a continuous measurement. For example, it could be used when comparing the outcome of a new analgesic drug using visual analogue pain scales as an outcome, comparing intervention and placebo. The SMC could be interpreted as the 'standardised' measure of outcome, where (assuming high scores denote more severe pain) if there were no difference between the interventions, the SMC would be zero, whilst a negative SMC would represent a reduction in pain. The SMC score is calculated by subtracting the follow up mean score in chosen outcome measure from the baseline mean score. This is then divided by its pooled SD, multiplied by a bias correction factor based on the group size ⁷¹. If the pooled SD was not reported, the baseline SD was used, or the SD at follow up. Estimates of the variance of the SMC were also calculated ⁷² and used to construct 95% confidence intervals. To allow for the repeated measures design, the within-group correlation was set at 0.5 for all studies ¹⁷.

Summarising the overall response to treatment

As the SMC standardises the measurement of change over time, studies using slightly different scales can be pooled together for comparison. As such, studies using modified or adjusted Constant scores were combined alongside those that reported unmodified scales. As for similar meta-analyses ³, one arm was then randomly selected per trial. This was because changes in outcome over time were of interest, rather than between arms comparison (e.g. to demonstrate superiority of one type of intervention). Intervention arms from each study are likely to be further correlated since participants recruited to each trial are likely to have similar characteristics and therefore have a similar response to treatment, which means that observations from different study arms would not be independent. Furthermore, the objective of this review was to describe the effect of treatments and not to estimate effect sizes between intervention groups.

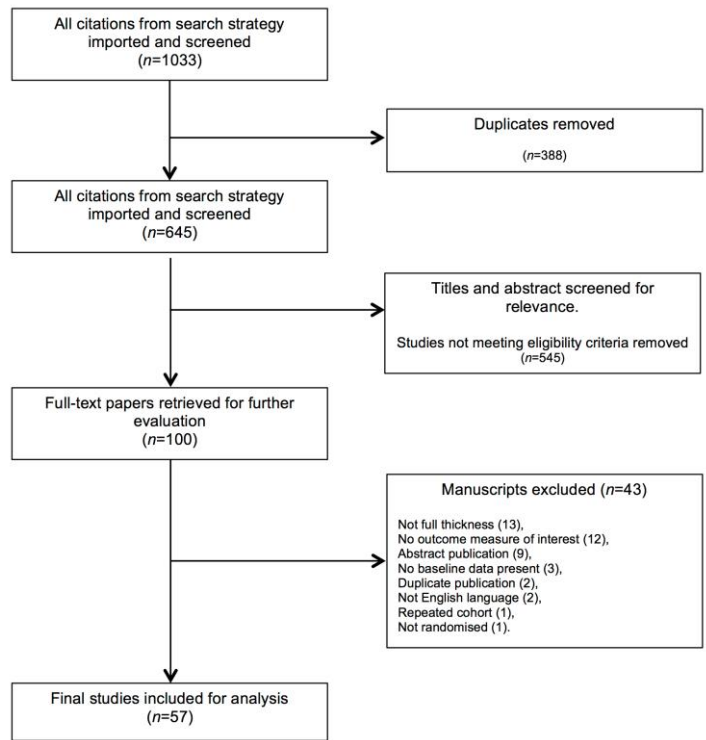
We calculated a combined pooled estimate of SMC for each time point using a random effects model. Studies were subcategorised according to treatment given to: (i) where primary repair was performed (ii) where acromioplasty was performed only (iii) conservative (non-operative) treatment. If patients had a primary repair and another treatment adjunct was applied (such as the application of platelet rich protein or acromioplasty) the study arm was allocated to repair group. We did a simple correlation analysis (using Pearson's correlation coefficient) on the SMCs between each time point to assess the relationship between each subsequent time point.

Analyses were conducted in R (Vienna, Austria) ⁸⁰ and using the metafor package ⁹².

Results

A total of 1033 citations were received from our search strategy. After removal of duplicates and screening of studies by title and abstract, 100 full text papers were retrieved. Out of these, 57 studies met our inclusion criteria from which 43 studies used the Constant score as an outcome measure (Figure 1). Of the 57 studies selected, 14 study authors were contacted for further information, however no responses were received.

Figure 1: Flow diagram detailing inclusion of studies into the review.



Description of studies included

With respect to studies reporting the Constant score; there were 39 studies with 73 arms that described treatment response for operative interventions of which eight studies with eight arms had repair and acromioplasty performed; two studies with two arms for acromioplasty only; five studies with seven arms were described for non-operative interventions. 26 studies with 53 arms reported the ASES score; 20 studies

with 40 treatment arms reported the UCLA score. The DASH was the least frequently reported score, with seven studies reporting 14 different treatment arms. A description of included studies is available in Table 1.

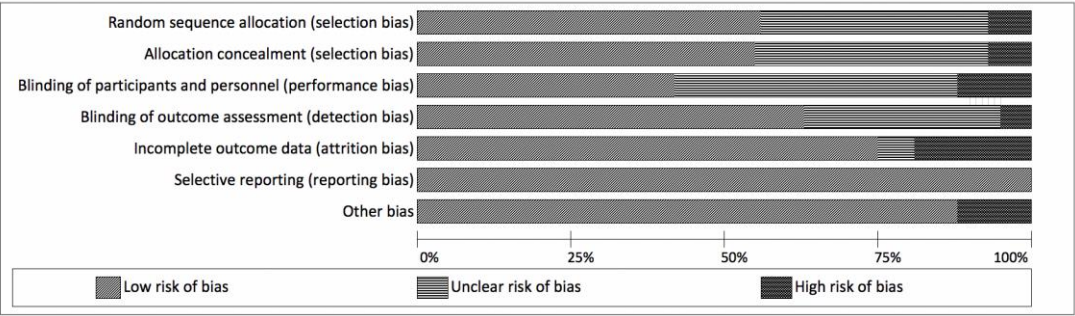
Description of patient population included

We included data from 4542 participants in this review, with study populations ranging from a minimum of 20 to 248 patients. Within the included studies, eight did not report gender. Of those that did report gender of patients included, 48% of participants were male. Four studies out of 57 did not report age; in those that did, the median of the mean reported age of participants was 59.0 (IQR 5.3). Of those studies included, 27 did not report dominant hand of included patients. From those studies reporting, 71% of participants had a full-thickness tear of their dominant side.

Risk of bias assessment

Studies included in this review had a low risk of bias for all domains apart from blinding of participants and personnel (performance bias); 42% (24/57) of studies had a low risk of performance bias: 47% (27/57) of studies had an unclear risk of bias (Figure 2).

Figure 2: Summary Table of Risk of Bias Assessment for Studies Included



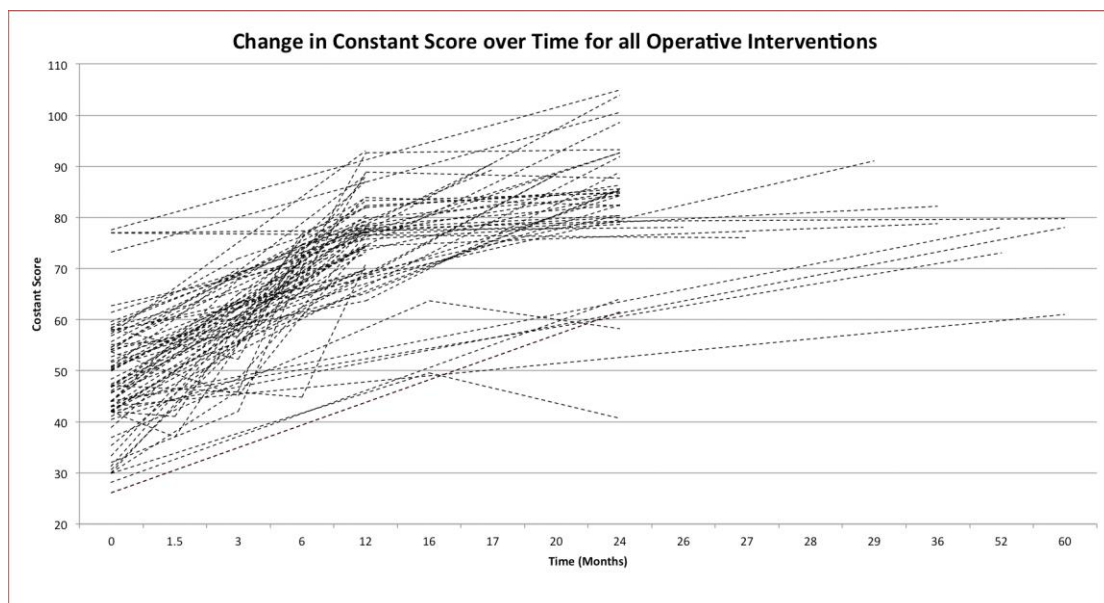
The general response to treatment

292

293 There was an overall improvement in all arms from baseline for studies reporting
294 Constant score (Figure 3). When exploring differences between operative and non-
295 operative arms, this effect was sustained, with all study arms showing positive
296 change. Treatment response in all outcome measures (ASES, UCLA and DASH)
297 showed an improvement in functional outcomes regardless of treatment intervention
298 applied (Figure 4). Studies that followed up patients at multiple time points indicate
299 an improvement in outcome in the first 12 months, following which the rate of
300 improvement stabilised. This pattern was consistent irrespective of treatment type
301 given (primary repair, acromioplasty only, or non-operative intervention).

302 **Figure 3:** Change in Constant score for all operative and non-operative interventions
303 over time (includes modified Constant score)

304



305

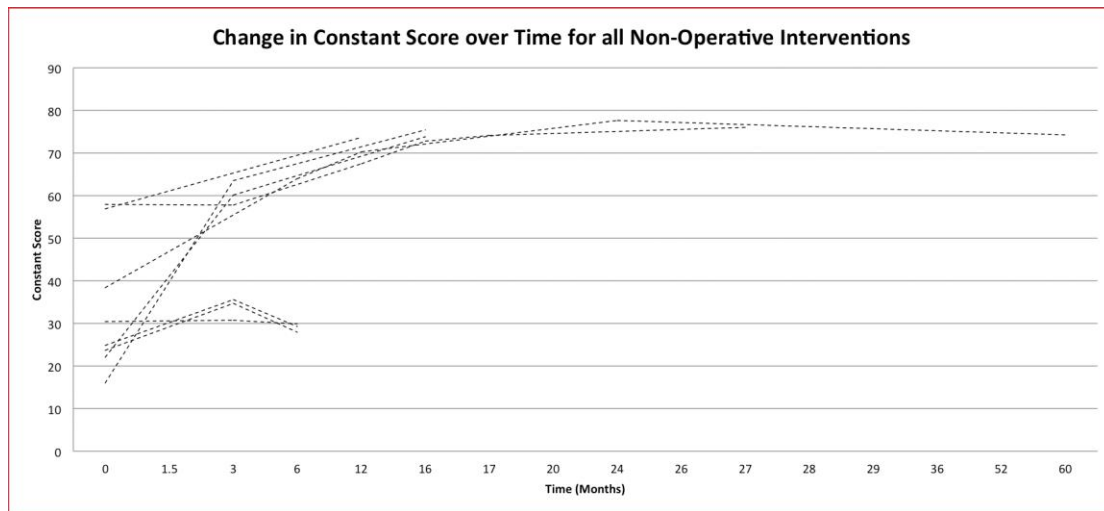
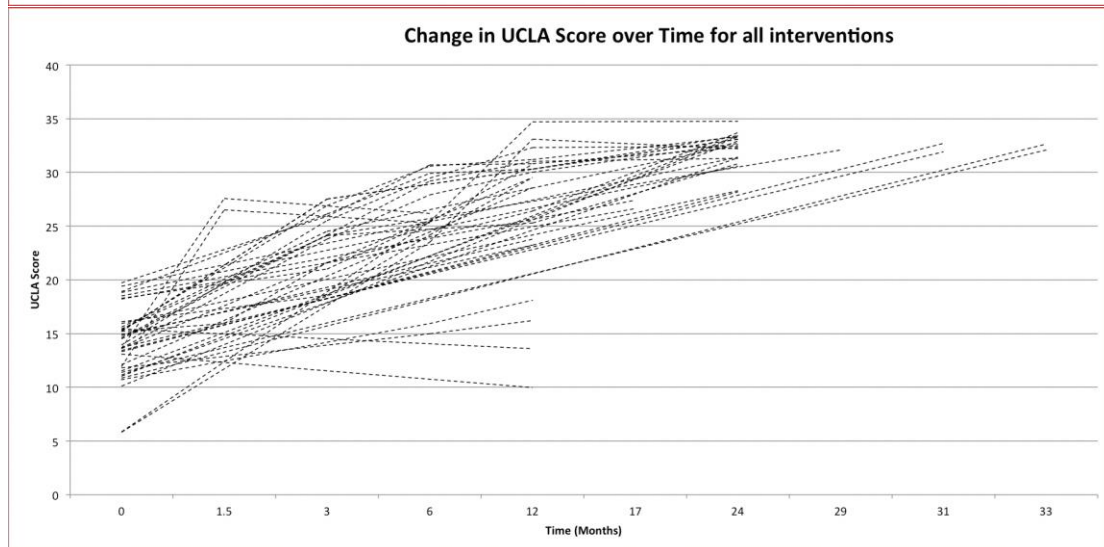
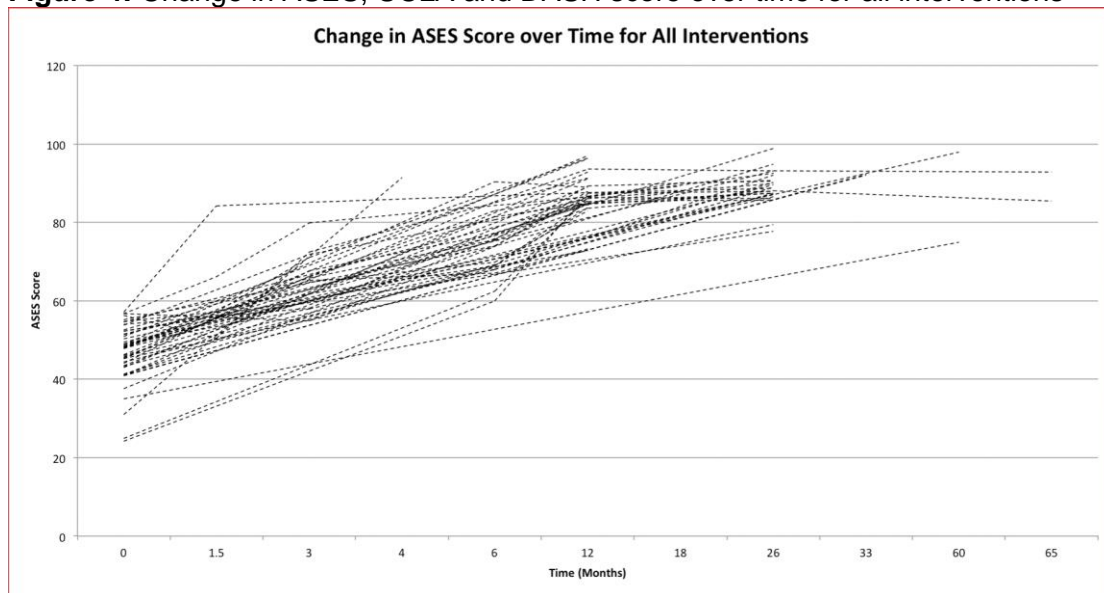
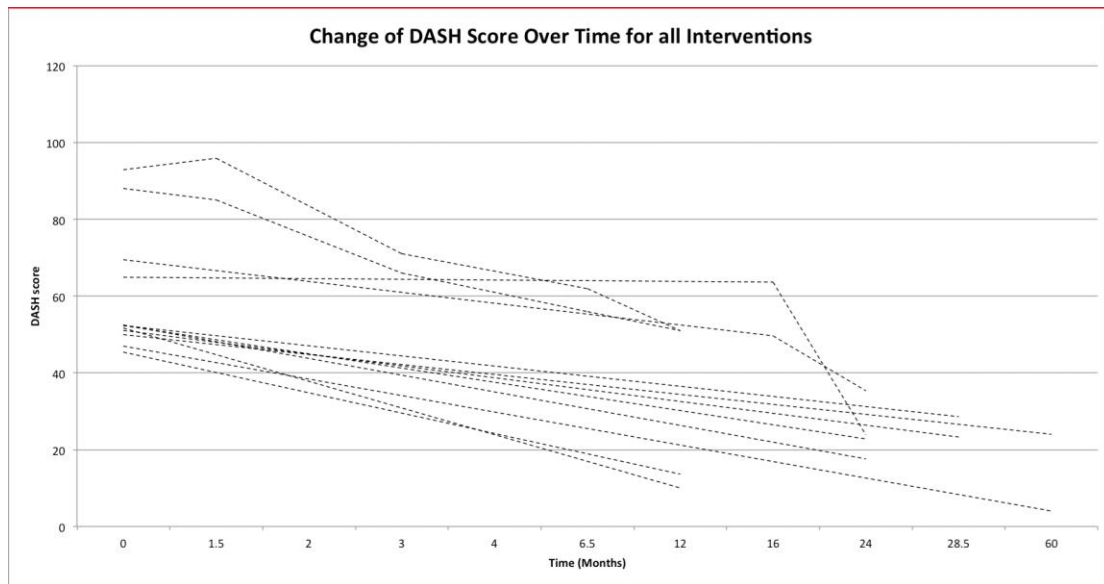


Figure 4: Change in ASES, UCLA and DASH score over time for all interventions





Summary of responses to treatments

A forest plot describing the pooled SMC from baseline for all sampled treatment arms was produced for the Constant Score (Figure 5). This showed a large pooled treatment response at 3 months (1.42 [95% CI 0.80-2.04]) and at 6 months (2.73 [95% CI 1.06-4.40]). The largest change was seen at 12 months (3.18 [95% CI 1.64-4.71], which then reduced slightly at 24 months (2.98 [95% CI 1.40-4.55]).

Figure 5: SMC for Constant score for one arm randomly selected from each trial arm at 3, 6, 12 and 24 months.

Figure 5: SMC for Constant score for one arm randomly selected from each trial arm at 3, 6, 12 and 24 months.

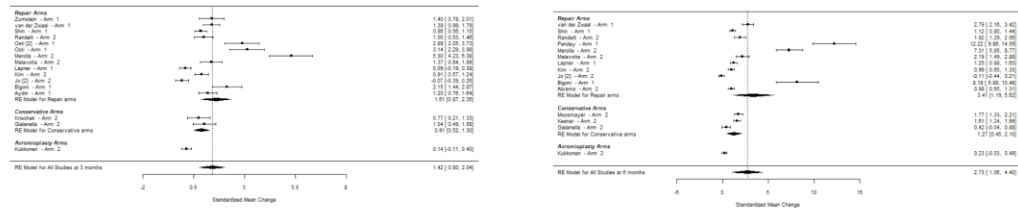


Figure 5a: Constant Score at 3 months

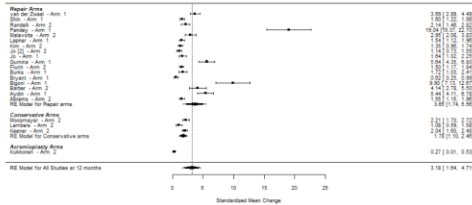


Figure 5b: Constant Score at 6 months

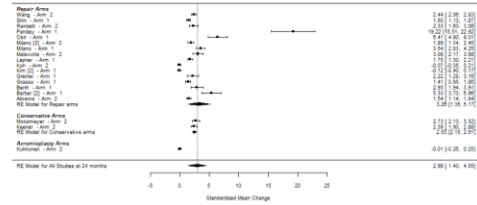


Figure 5c: Constant Score at 12 months

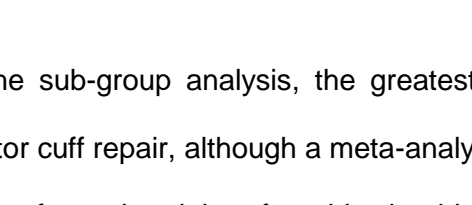
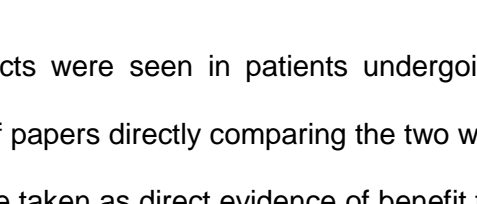


Figure 5d: Constant Score at 24 months



In the sub-group analysis, the greatest effects were seen in patients undergoing rotator cuff repair, although a meta-analysis of papers directly comparing the two was not performed and therefore this should not be taken as direct evidence of benefit for repair. Trends in the effects followed the same pattern as observed in the main analysis, with the largest effects observed at 12 months with a SMC of 3.65 (95% CI 1.74-5.56) for patients undergoing repair compared to 1.78 (95% CI 1.10-2.46) for conservative and 0.27 (95% CI 0.01-0.53) for acromioplasty patients.

There was strong correlation in SMCs for each time point, which increased as the studies progressed. The Pearson's correlation coefficients were 0.816 (n=11, 95% CI 0.424 to 0.951) between 3 months and 6 months, 0.987 (n=13, 95% CI 0.957 to 0.996) between 6 months and 12 months and 0.999 (n=9, 95% CI 0.996 to 1.00) between 12 months and 24 months.

Discussion

We aimed to collate the evidence on the short-term natural history of patients with symptomatic full-thickness rotator cuff tears, regardless of the treatment they received. The studies included in this review examined a wide variety of treatment modalities, including a variety of operative techniques as well as non-operative interventions. This review found that treatment response follows a similar pattern of rapid improvement in the first 12 months after an intervention, after which the recovery plateaus. This pattern was found in all treatment arms irrespective of intervention applied, including either surgical or non-surgical care.

Whilst assessing the natural history of a condition using randomised trial data alone may seem counter-intuitive, there are a number of good reasons for doing so. Randomised trials typically have well organised follow-up arrangements at fixed time periods from randomisation, which are usually pre-defined. By definition, they are prospective studies in well-defined populations. A well-constructed cohort study can achieve all of these things but this is harder to detect and assess when reviewing a paper, and many cohort studies suffer from being conducted with cross-sectional sampling, meaning that follow-up times vary considerably from the intervention. This may be valuable in a long-term follow up study, but the purpose of this study was to examine short to medium-term outcomes (that is, in the first few months and years after the intervention) and as such, randomised trials provide a wealth of prospective data with fixed time points for follow up.

In determining an explanation for the patterns that were observed, consideration must be given to the natural history of rotator cuff tears. Previously conducted systematic reviews have commented on the scarcity of studies investigating the topic²⁶. A cohort study by Safran and colleagues assessing the natural history in

365 symptomatic, full-thickness rotator cuff tears who were treated non-operatively found
366 that patients often had progression in tear size which was linked to a deterioration in
367 pain ⁸⁶. This is different to our findings, where we found non-operatively treated
368 patients improve in outcome measures. In the above study, it is not explained why
369 their cohort was treated non-operatively, as perhaps these patients may have been
370 unsuitable for operative intervention. On comparison, in half of the studies included in
371 this review with a non-operative arm, participants would have been suitable for an
372 operative intervention. In addition, people included in studies with only non-operative
373 arms may not have had significant disability to seek operative intervention. As such
374 this may represent two different sub-sections of the population.

375
376 Moosmayer found that patients with asymptomatic rotator cuff tears often progressed
377 to become symptomatic, representing a structural deterioration of the rotator cuff ⁷⁰.
378 However, this patient cohort differs from those entered into randomised controlled
379 trials, as asymptomatic patients are unlikely to actively seek healthcare. In contrast,
380 patients seeking surgical treatment are likely to represent a sub-section of the
381 population with the worst symptoms, leading to lower baseline outcome scores. As
382 such, these patients also represent those who have the potential for larger reductions
383 in symptoms and therefore the greatest treatment response.

384
385 The phenomenon of regression to the mean is a ubiquitous statistical occurrence in
386 repeated data. This suggests that if a variable is extreme on its first measurement, it
387 will tend to be closer to the population mean on subsequent measurements ⁷³. In
388 other words, if a patient's pain varies, they will typically see a specialist and be
389 entered for treatment (or into a study) when the pain is at its peak, and in future
390 measurements it will be reduced as the pain then falls from that previous peak. As
391 such, patients with worse baseline outcome measures represent those with greater
392 potential to improve due to regression to the mean. Equally, it may be that patients

who present with pain and symptoms will recover with time and patient care, as implied by these studies where there is a large effect and regression to the mean may seem to be unlikely. In reality, it is difficult to separate the effects of regression to the mean from the true natural history of full-thickness tears.

Thought must also be given to non-specific factors for change in outcomes. Indeed, there is evidence to suggest participation in randomised controlled trials may itself confer benefit to patients ¹³. This effect is particularly seen in situations where effective treatments are included in the trial protocol ¹³, such as for many studies included in this review. Other factors, such as trust in health care professional delivering treatment ¹⁰ and the manner in which patients expectations for treatment response is enhanced by positive information ¹¹ all significantly contribute to the improvement of health outcomes. In addition, attributes from the patient including their expectation, emotions and psychological conditioning have been found to be of positive influence ^{52,79}. Perhaps the best recognised is the role of the placebo in influencing outcomes. Whilst its influence within drug trials is well established, there is evidence for its use as an effective treatment in other chronic musculoskeletal conditions ⁹⁷. Furthermore, the placebo can be augmented with previously mentioned factors such as clinician warmth ⁴⁵. Again it is difficult to estimate the effect of these factors into the trials included in this study.

One other consideration is the timing of outcomes in randomised studies. It is common for reviewers to insist on 24-month outcomes, however we found that they add little value beyond 12 months. After 12 months in all treatment arms, the improvement stabilised, and correlations in scores at different time points were very high. In other words, once the 12-month outcomes were known then the 24-month outcomes were highly predictable. We recommend a 12-month primary outcome based on our findings. This has important implications in the delivery of randomised

421 trials, which are often expensive and time consuming, and reporting at 12 rather than
422 24 months would save substantial cost as well as time in producing an answer that
423 can be delivered to improved clinical care for patients, whereas waiting for a 24
424 month follow-up adds little. This is not to say that later follow-up (say, five or ten
425 year) does not add different or valuable information, but in terms of short to medium-
426 term outcomes, a primary outcome at 12 months can be recommended based on our
427 findings.

428
429 Surgical treatments may be effective, although their true effect over non-operative
430 treatment is likely to be much less than the effect that seen in uncontrolled case-
431 series. Our data show that such an improvement may also be seen with conservative
432 treatments. The overall effect of surgery can only be assessed by comparing surgery
433 to conservative treatment, and consideration should also be given sham or placebo
434 controlled trials of surgery ^{31,94}. When assessing the results of surgical procedures,
435 and surgeons should be aware of the natural history of symptomatic cuff tears in the
436 short term to improve substantially with conservative care alone when they assess
437 the result of other treatments or procedures.

438 439 *Strengths and Limitations*

440
441 This study was conducted and reported in accordance with the PRISMA guidelines
442 ⁶⁷. It was conducted with a pre-defined and published study protocol.

443
444 We used the Constant score as its primary outcome measure. It is the most widely
445 used assessment tool ⁵¹ and was the most frequently outcome measure in studies
446 included in this review thus giving the greatest volume of data to pool. Other
447 measures used in this review including ASES, UCLA score and the DASH score
448 were next commonly reported and thus represented an appropriate secondary

outcome measures. A small number of trials used other measures such as change in visual analogue score, or purely radiological outcome measures, which were therefore not included. As these were so infrequently reported and varied in their definitions, any meaningful pooling of this data would not have been possible.

Only trials with fully published outcome measures were included. Thus, there is a risk of publication bias from studies with incomplete outcome data, which were excluded from the study analysis. In line with Cochrane guidelines, authors of the papers were contacted with reasonable efforts in order to minimise this. A further limitation is that only English language studies were included. However, this results in only two studies being excluded and those that were included were from a wide distribution geographically. The large number of included studies showing consistent results suggests it is unlikely that our conclusions would be changed if any other such studies had been included.

This study has not been designed as a meta-analysis to directly compare rotator cuff repair, acromioplasty or physiotherapy, and rather is a description of the natural history of each treatment. Conclusions on the relative merits of the treatments should not be directly inferred from these findings. Different studies are included which may have had different populations in them. An example of this is the apparent worse performance of acromioplasty relative to repair or conservative care. Whilst the study did adjust for baseline scores, the different studies are not necessarily the same population of patients or types of tear, so care should be taken in over-interpreting our findings. However, it makes an important statement about the likely outcome of patients with symptomatic cuff tears over time, and this needs to be considered when interventions such as surgery are being considered, or when other treatments are being evaluated.

477 We did not assess the long-term outcomes of these patients. Certainly, it is
478 established that massive rotator cuff tears can lead to the development of rotator cuff
479 arthropathy ²⁴. This may then result in a deterioration of outcomes and there is
480 evidence to suggest early repair of rotator cuff tears can prevent progression into
481 rotator cuff arthropathy ^{19,74}. Unfortunately long term outcomes were beyond the
482 scope of this review as it was based on trial data, which typically does not extend
483 long enough to assess long-term outcomes.

Conclusions

We have shown that patients with symptomatic full-thickness rotator cuff tears demonstrate a consistent and considerable response to treatment, even with conservative management. The largest improvement occurs in the first 12 months, after which the response stabilises. When assessing the treatment effect of invasive surgery, consideration must be given to the natural history of patients with rotator cuff tears to improve over time with non-operative care as well.

Funding

There was no funding allocated for this systematic review.

References

1. Abrams GD, Gupta AK, Hussey KE, et al. Arthroscopic Repair of Full-Thickness Rotator Cuff Tears With and Without Acromioplasty: Randomized Prospective Trial With 2-Year Follow-up. *Am J Sports Med.* 2014;42(6):1296-1303.
2. Amstutz HC, Sew Hoy AL, Clarke IC. UCLA anatomic total shoulder arthroplasty. *Clin Orthop Relat Res.* (155):7-20.
3. Artus M, van der Windt DA, Jordan KP, Hay EM. Low back pain symptoms show a similar pattern of improvement following a wide range of primary care treatments: A systematic review of randomized clinical trials. *Rheumatology.* 2010;49(12):2346-2356.
4. Artus M, van der Windt D, Jordan KP, Croft PR. The clinical course of low back pain: a meta-analysis comparing outcomes in randomised clinical trials (RCTs) and observational studies. *BMC Musculoskelet Disord.* 2014;15(1):68..
5. Aydin N, Kocaoglu B, Guven O. Single-row versus double-row arthroscopic rotator cuff repair in small- to medium-sized tears. *J Shoulder Elb Surg.* 2010;19(5):722-725.
6. Barber F a, Burns JP, Deutsch a, Labbe MR, Litchfield RB. A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. *Arthrosc J Arthrosc Relat Surg.* 2012;28(1):8-15..
7. Berth A, Neumann W, Awiszus F, Pap G. Massive rotator cuff tears: functional outcome after debridement or arthroscopic partial repair. *J Orthop Traumatol.* 2010;11(1):13-20.
8. Bidwai ASC, Birch A, Temperley D, et al. Medium- to long-term results of a randomized controlled trial to assess the efficacy of arthoscopic-subacromial decompression versus mini-open repair for the treatment of medium-sized rotator cuff tears. *Shoulder Elb.* 2016;8(2):101-105.
9. Bigoni M, Gorla M, Guerrasio S, et al. Shoulder evaluation with isokinetic strength testing after arthroscopic rotator cuff repairs. *J Shoulder Elbow Surg.* 2009;18(2):178-183.
10. Birkhäuser J, Gaab J, Kossowsky J, et al. Trust in the health care professional and health outcome: A meta-analysis. *PLoS One.* 2017;12(2):e0170988.
11. Blasi Z Di, Harkness E, Ernst E, Georgiou A, Kleijnen J. Influence of context effects on health outcomes: a systematic review. *Lancet.* 2001;357(9258):757-762.
12. Boehm TD, Werner A, Radtke S, Mueller T, Kirschner S, Gohlke F. The effect of suture materials and techniques on the outcome of repair of the rotator cuff. *J Bone Jt Surg - Ser B.* 2005;87(6):819-823.
13. Braunholtz DA, Edwards SJL, Lilford RJ. Are randomized clinical trials good for us (in the short term)? Evidence for a "trial effect." *J Clin Epidemiol.* 2001;54(3):217-224.
14. Bryant D, Holtby R, Willits K, et al. A randomized clinical trial to compare the effectiveness of rotator cuff repair with or without augmentation using porcine small intestine submucosa for patients with moderate to large rotator cuff tears: a pilot study. *J Shoulder Elbow Surg.* 2016.
15. Burks RT, Crim J, Brown N, Fink B, Greis PE. A prospective randomized clinical trial comparing arthroscopic single- and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. *Am J Sports Med.* 2009;37(4):674-682.
16. Carbonel I, Martinez A, Calvo A, Ripalda J, Herrera A. Single-row versus double-row arthroscopic repair in the treatment of rotator cuff tears: A prospective randomized clinical study. *Int Orthop.* 2012;36(9):1877-1883.
17. Carr AJ, Cooper CD, Campbell MK, et al. Clinical effectiveness and cost-effectiveness of open and arthroscopic rotator cuff repair [the UK Rotator Cuff

552 Surgery (UKUFF) randomised trial]. *Health Technol Assess*. 2015;19(80):1-
553 218.

554 18. Castricini R, Longo UG, De Benedetto M, et al. Platelet-rich plasma
555 augmentation for arthroscopic rotator cuff repair: a randomized controlled trial.
556 *Am J Sports Med*. 2011;39(2):258-265.

557 19. Clement ND, Nie YX, McBirnie JM. Management of degenerative rotator cuff
558 tears: a review and treatment strategy. *Sports Med Arthrosc Rehabil Ther*
559 *Technol*. 2012;4(1):48.

560 20. Constant CR, Murley AH. A clinical method of functional assessment of the
561 shoulder. *Clin Orthop Relat Res*. 1987;(214):160-164.

562 21. Cuff DJ, Pupello DR. Prospective randomized study of arthroscopic rotator cuff
563 repair using an early versus delayed postoperative physical therapy protocol. *J*
564 *Shoulder Elbow Surg*. 2012;21(11):1450-1455.

565 22. Dezaly C, Sirveaux F, Philippe R, et al. Arthroscopic treatment of rotator cuff
566 tear in the over-60s: Repair is preferable to isolated acromioplasty-tenotomy in
567 the short term. *Orthop Traumatol Surg Res*. 2011;97(6 SUPPL.):S125-S130.

568 23. Duzgun I, Baltaci G, Atay OA. Comparison of slow and accelerated
569 rehabilitation protocol after arthroscopic rotator cuff repair: pain and functional
570 activity. *Acta Orthop Traumatol Turc*. 2011;45(1):23-33.

571 24. Ecklund KJ, Lee TQ, Tibone J, Gupta R. Rotator cuff tear arthropathy. *J Am*
572 *Acad Orthop Surg*. 2007;15(6):340-349.

573 25. Edwards P, Ebert J, Joss B, Bhabra G, Ackland T, Wang A. Exercise
574 rehabilitation in the non-operative management of rotator cuff tears: A review
575 of the literature. *Int J Sports Phys Ther*. 2016;11(2):279-301.

576 26. Eljabu W, Klinger HM, von Knoch M. The natural history of rotator cuff tears: a
577 systematic review. *Arch Orthop Trauma Surg*. 2015;135(8):1055-1061.

578 27. Ensor KL, Kwon YW, DiBeneditto MR, Zuckerman JD, Rokito AS. The rising
579 incidence of rotator cuff repairs. *J Shoulder Elb Surg*. 2013;22(12):1628-1632.

580 28. Flurin P-H, Hardy P, Abadie P, et al. Rotator cuff tears after 70years of age: A
581 prospective, randomized, comparative study between decompression and
582 arthroscopic repair in 154 patients. *Orthop Traumatol Surg Res*. 2013;99(8
583 S):S371-S378.

584 29. Franceschi F, Ruzzini L, UG L, et al. Equivalent clinical results of arthroscopic
585 single-row and double-row suture anchor repair for rotator cuff tears: a
586 randomized controlled trial. *Am J Sports Med*. 2007;35(8):1254-1260.

587 30. Gartsman GM, O'connor DP. Arthroscopic rotator cuff repair with and without
588 arthroscopic subacromial decompression: a prospective, randomized study of
589 one-year outcomes. *J Shoulder Elbow Surg*. 2004;13(4):424-426.

590 31. George A, Collett C, Carr A, et al. When should placebo surgery as a control
591 in clinical trials be carried out? *Bull R Coll Surg Engl*. 2016;98(2):75-79.

592 32. Gialanella B, Prometti P. Effects of Corticosteroids Injection in Rotator Cuff
593 Tears. *Pain Med*. 2011;12(10):1559-1565.

594 33. Grasso A, Milano G, Salvatore M, Falcone G, Deriu L, Fabbriani C. Single-
595 row versus double-row arthroscopic rotator cuff repair: a prospective
596 randomized clinical study. *Arthrosc J Arthrosc Relat Surg*. 2009;25(1):4-12.

597 34. Green edited by JPTH and S. *Cochrane Handbook for Systematic Reviews of*
598 *Interventions*. Chichester, West Sussex ; Hoboken NJ : John Wiley & Sons,
599 [2008].

600 35. Greiner S, Schmidt C, Herrmann S, Pauly S, Perka C. Clinical performance of
601 lateralized versus non-lateralized reverse shoulder arthroplasty: A prospective
602 randomized study. *J Shoulder Elb Surg*. 2015;24(9):1397-1404.

603 36. Gumina S, Campagna V, Ferrazza G, et al. Use of platelet-leukocyte
604 membrane in arthroscopic repair of large rotator cuff tears: A prospective
605 randomized study. *J Bone Jt Surg - Ser A*. 2012;94(15):1345-1352.

606 37. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's

607 tool for assessing risk of bias in randomised trials. . *Br Med J*. 2011;343:889-
608 893.

609 38. Huang R, Wang S, Wang Y, Qin X, Sun Y. Systematic Review of All-
610 Arthroscopic Versus Mini-Open Repair of Rotator Cuff Tears: A Meta-Analysis.
611 *Sci Rep*. 2016;6:22857.

612 39. Hudak PL, Amadio PC, Bombardier C, et al. Development of an upper
613 extremity outcome measure: The DASH (disabilities of the arm, shoulder, and
614 head). *Am J Ind Med*. 1996;29(6):602-608.

615 40. Huisstede BMA, Koes BW, Gebremariam L, Keijsers E, Verhaar JAN. Current
616 evidence for effectiveness of interventions to treat rotator cuff tears. *Man Ther*.
617 2011;16(3):217-230.

618 41. JA C, Buchbinder R, Green S, RV J, SN B. Surgery for rotator cuff disease.
619 *Cochrane Database Syst Rev*. January 2008:N.PAG-N.PAG.

620 42. Jacquot A, Dezaly C, Goetzmann T, Roche O, Sirveaux F, Molé D. Is rotator
621 cuff repair appropriate in patients older than 60 years of age? Prospective,
622 randomised trial in 103 patients with a mean four-year follow-up. *Orthop*
623 *Traumatol Surg Res*. 2014;100(6):S333-S338.

624 43. Jo CH, Shin JS, Lee YG, et al. Platelet-Rich Plasma for Arthroscopic Repair of
625 Large to Massive Rotator Cuff Tears: A Randomized, Single-Blind, Parallel-
626 Group Trial. *Am J Sports Med*. 2013;41(10):2240-2248.

627 44. Jo CH, Shin JS, Shin WH, Lee SY, Yoon KS, Shin S. Platelet-Rich Plasma for
628 Arthroscopic Repair of Medium to Large Rotator Cuff Tears: A Randomized
629 Controlled Trial. *Am J Sports Med*. 2015;43(9):2102-2110.

630 45. Kaptchuk TJ, Kelley JM, Conboy LA, et al. Components of placebo effect:
631 randomised controlled trial in patients with irritable bowel syndrome. *Br Med J*.
632 2008;336(7651):999-1003.

633 46. Keener JD, Galatz LM, Stobbs-Cucchi G, Patton R, Yamaguchi K.
634 Rehabilitation following arthroscopic rotator cuff repair: a prospective
635 randomized trial of immobilization compared with early motion. *J Bone Joint*
636 *Surg Am*. 2014;96(1):11-19.

637 47. Kim J, Chung J, Ok H. Asymptomatic acromioclavicular joint arthritis in
638 arthroscopic rotator cuff tendon repair: a prospective randomized comparison
639 study. *Arch Orthop Trauma Surg*. 2011;131(3):363-369.

640 48. Kim JY, Lee JS, Park CW. Extracorporeal shock wave therapy is not useful
641 after arthroscopic rotator cuff repair. *Knee Surgery, Sport Traumatol Arthrosc*.
642 2012;20(12):2567-2572.

643 49. Kim Y-S, Chung SW, Kim JY, Ok J-H, Park I, Oh JH. Is Early Passive Motion
644 Exercise Necessary After Arthroscopic Rotator Cuff Repair? *Am J Sports Med*.
645 2012;40(4):815-821.

646 50. Kim Y-S, Lee H-J, Jin H-K, Kim S-E, Lee J-W. Conventional En Masse Repair
647 Versus Separate Double-Layer Double-Row Repair for the Treatment of
648 Delaminated Rotator Cuff Tears. *Am J Sports Med*. 2016.

649 51. Kirkley A, Griffin S, Dainty K. Scoring Systems for the Functional Assessment
650 of the Shoulder. *Arthrosc - J Arthrosc Relat Surg*. 2003;19(10):1109-1120.

651 52. Klinger R, Soost S, Flor H, Worm M. Classical conditioning and expectancy in
652 placebo hypoalgesia: A randomized controlled study in patients with atopic
653 dermatitis and persons with healthy skin. *Pain*. 2007;128(1-2):31-39.

654 53. Koh KH, Lim TK, Shon MS, Park YE, Lee SW, Yoo JC. Effect of
655 immobilization without passive exercise after rotator cuff repair: randomized
656 clinical trial comparing four and eight weeks of immobilization. *J Bone Joint*
657 *Surg Am*. 2014;96(6):e44.

658 54. Krischak G, Gebhard F, Reichel H, et al. A prospective randomized controlled
659 trial comparing occupational therapy with home-based exercises in
660 conservative treatment of rotator cuff tears. *J Shoulder Elb Surg*.
661 2013;22(9):1173-1179.

- 662 55. Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of nontraumatic rotator
663 cuff tears: A randomized controlled trial with two years of clinical and imaging
664 follow-up. *J Bone Jt Surg - Am Vol.* 2015;97(21):1729-1737.
- 665 56. Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of Nontraumatic
666 Rotator Cuff Tears: A Randomized Controlled Trial with Two Years of Clinical
667 and Imaging Follow-up. *J Bone Joint Surg Am.* 2015;97(21):1729-1737.
- 668 57. Lambers Heerspink FO, van Raay JJAM, Koorevaar RCT, et al. Comparing
669 surgical repair with conservative treatment for degenerative rotator cuff tears:
670 A randomized controlled trial. *J Shoulder Elb Surg.* 2015;24(8):1274-1281.
- 671 58. Lapner PLC, Sabri E, Rakhra K, et al. A multicenter randomized controlled trial
672 comparing single-row with double-row fixation in arthroscopic rotator cuff
673 repair. *J Bone Jt Surg - Ser A.* 2012;94(14):1249-1257.
- 674 59. Ma HL, Chiang ER, Wu HTH, et al. Clinical outcome and imaging of
675 arthroscopic single-row and double-row rotator cuff repair: A prospective
676 randomized trial. *Arthrosc - J Arthrosc Relat Surg.* 2012;28(1):16-24.
- 677 60. MacDonald P, McRae S, Leiter J, Mascarenhas R, Lapner P. Arthroscopic
678 rotator cuff repair with and without acromioplasty in the treatment of full-
679 thickness rotator cuff tears: a multicenter, randomized controlled trial. *J Bone
680 Joint Surg Am.* 2011;93(21):1953-1960.
- 681 61. Makhni EC, Hamamoto JT, Higgins JD, et al. How Comprehensive and
682 Efficient Are Patient-Reported Outcomes for Rotator Cuff Tears? *Orthop J
683 Sport Med.* 2017;5(3):232596711769322.
- 684 62. Malavolta EA, Gracitelli MEC, Ferreira Neto AA, et al. Platelet-Rich Plasma in
685 Rotator Cuff Repair: A Prospective Randomized Study. *Am J Sports Med.*
686 2014;42(10):2446-2454.
- 687 63. Merolla G, Dellabiancia F, Ingardia A, Paladini P, Porcellini G. Co-analgesic
688 therapy for arthroscopic supraspinatus tendon repair pain using a dietary
689 supplement containing *Boswellia serrata* and *Curcuma longa*: a prospective
690 randomized placebo-controlled study. *Musculoskelet Surg.* 2015;99:43-52.
- 691 64. Milano G, Grasso A, Salvatore M, Saccomanno MF, Deriu L, Fabbriani C.
692 Arthroscopic Rotator Cuff Repair With Metal and Biodegradable Suture
693 Anchors: A Prospective Randomized Study. *Arthrosc J Arthrosc Relat Surg.*
694 2010;26(9):S112-S119.
- 695 65. Milano G, Saccomanno MF, Careri S, Taccardo G, De Vitis R, Fabbriani C.
696 Efficacy of marrow-stimulating technique in arthroscopic rotator cuff repair: a
697 prospective randomized study. *Arthroscopy.* 2013;29(5):802-810.
- 698 66. Mj P, Green S, McBain B, et al. Manual therapy and exercise for rotator cuff
699 disease (Review). *Cochrane Database Syst Rev.* 2016;(6).
- 700 67. Moher D, Liberati A, Tetzlaff J, Altman DG, Altman D. Preferred Reporting
701 Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement.
702 *PLoS Med.* 2009;6(7):e1000097.
- 703 68. Mohtadi NG, Hollinshead RM, Sasyniuk TM, Fletcher JA, Chan DS, Li FX. A
704 randomized clinical trial comparing open to arthroscopic acromioplasty with
705 mini-open rotator cuff repair for full-thickness rotator cuff tears: Disease-
706 specific quality of life outcome at an average 2-year follow-up. *Am J Sports
707 Med.* 2008;36(6):1043-1051.
- 708 69. Moosmayer S, Lund G, Seljom US, et al. Tendon repair compared with
709 physiotherapy in the treatment of rotator cuff tears: a randomized controlled
710 study in 103 cases with a five-year follow-up. *J Bone Joint Surg Am.*
711 2014;96(18):1504-1514.
- 712 70. Moosmayer S, Tariq R, Stiris M, Smith H-J. The Natural History of
713 Asymptomatic Rotator Cuff Tears. *J Bone Jt Surg Am.* 2013;95(14):1249-
714 1255.
- 715 71. Morris SB. Estimating Effect Sizes From Pretest-Posttest-Control Group
716 Designs. *Organ Res Methods.* 2008;11(2):364-386.

- 717 72. Morris SB. Estimating Effect Sizes From Pretest-Posttest-Control Group
718 Designs. *Organ Res Methods*. 2008;11(2):364-386.
- 719 73. Morton V, Torgerson DJ. Regression to the mean: treatment effect without the
720 intervention. *J Eval Clin Pract*. 2005;11(1):59-65.
- 721 74. Neer CS, Craig E V, Fukuda H. Cuff-tear arthropathy. *J Bone Joint Surg Am*.
722 1983;65(9):1232-1244.
- 723 75. Osti L, Del Buono A, Maffulli N. Microfractures at the rotator cuff footprint: a
724 randomised controlled study. *Int Orthop*. 2013;37(11):2165-2171. 1.
- 725 76. Osti L, Buono A Del, Maffulli N. Pulsed electromagnetic fields after rotator cuff
726 repair: a randomized, controlled study. *Orthopedics*. 2015;38(3):e223-8.
- 727 77. P van der Z, BJ T, MJ N, Lindenburg R, JW S, ER van A. Clinical Outcome in
728 All-Arthroscopic Versus Mini-Open Rotator Cuff Repair in Small to Medium-
729 Sized Tears: A Randomized Controlled Trial in 100 Patients With 1-Year
730 Follow-up. *Arthrosc J Arthrosc Relat Surg*. 2013;29(2):266-273..
- 731 78. Pandey V, Bandi A, Madi S, et al. Does application of moderately
732 concentrated platelet-rich plasma improve clinical and structural outcome after
733 arthroscopic repair of medium-sized to large rotator cuff tear? A randomized
734 controlled trial. *J Shoulder Elbow Surg*. 2016;25(8):1312-1322.
- 735 79. Price DD, Chung SK, Robinson ME. Conditioning, expectation, and desire for
736 relief in placebo analgesia. *Semin Pain Med*. 2005;3(1 SPEC. ISS.):15-21.
- 737 80. R Core Team. R: A language and environment for statistical computing.
738 <https://www.r-project.org/>.
- 739 81. Randelli P, Arrigoni P, Ragone V, Aliprandi A, Cabitza P. Platelet rich plasma
740 in arthroscopic rotator cuff repair: a prospective RCT study, 2-year follow-up. *J*
741 *Shoulder Elbow Surg*. 2011;20(4):518-528..
- 742 82. Reilly P, Macleod I, Macfarlane R, Windley J, Emery RJH. Dead men and
743 radiologists don't lie: A review of cadaveric and radiological studies of rotator
744 cuff tear prevalence. *Ann R Coll Surg Engl*. 2006;88(2):116-121.
- 745 83. Richards RR, An K-N, Bigliani LU, et al. A standardized method for the
746 assessment of shoulder function. *J Shoulder Elb Surg*. 1994;3(6):347-352.
- 747 84. Rodeo SA, Delos D, Williams RJ, Adler RS, Pearle A, Warren RF. The effect
748 of platelet-rich fibrin matrix on rotator cuff tendon healing: a prospective,
749 randomized clinical study. *Am J Sports Med*. 2012;40(6):1234-1241.
- 750 85. Ruiz-Moneo P, Molano-Munoz J, Prieto E, Algorta J. Plasma rich in growth
751 factors in arthroscopic rotator cuff repair: A randomized, double-blind,
752 controlled clinical trial. *Arthrosc - J Arthrosc Relat Surg*. 2013;29(1):2-9.
- 753 86. Safran O, Schroeder J, Bloom R, Weil Y, Milgrom C. Natural History of
754 Nonoperatively Treated Symptomatic Rotator Cuff Tears in Patients 60 Years
755 Old or Younger. *Am J Sports Med*. 2011;39(4):710-714.
- 756 87. SH K, CC L, Friedman D, KB P, JJ W. Arthroscopic single-row supraspinatus
757 tendon repair with a modified mattress locking stitch: a prospective,
758 randomized controlled comparison with a simple stitch. *Arthrosc J Arthrosc*
759 *Relat Surg*. 2008;24(9):1005-1012.
- 760 88. Shibata Y, Midorikawa K, Emoto G, Naito M. Clinical evaluation of sodium
761 hyaluronate for the treatment of patients with rotator cuff tear. *J Shoulder*
762 *Elbow Surg*. 2001;10(3):209-216.
- 763 89. Shin SJ, Oh JH, Chung SW, Song MH. The efficacy of acromioplasty in the
764 arthroscopic repair of small- to medium-sized rotator cuff tears without
765 acromial spur: Prospective comparative study. *Arthrosc - J Arthrosc Relat*
766 *Surg*. 2012;28(5):628-635.
- 767 90. Thorlund JB, Juhl CB, Roos EM, Lohmander LS. Arthroscopic surgery for
768 degenerative knee: systematic review and meta-analysis of benefits and
769 harms. *Br J Sports Med*. 2015;49(19):1229-1235.
- 770 91. Triple-Loaded Single-Row Versus Suture-Bridge Double-Row Rotator Cuff
771 Tendon Repair with Platelet-Rich Plasma Fibrin Membrane: A Randomized

772 Controlled Trial. *Arthrosc - J Arthrosc Relat Surg*. 2016;32(5):753-761.

773 92. Viechtbauer W. Conducting Meta-Analyses in R with the **metafor** Package. *J*
774 *Stat Softw*. 2010;36(3):1-48. doi:10.18637/jss.v036.i03.

775 93. Wang E, Wang L, Gao P, Li Z, Zhou X, Wang S. Single-versus double-row
776 arthroscopic rotator cuff repair in massive tears. *Med Sci Monit*. 2015;21:1556-
777 1561.

778 94. Wartolowska KA, Collins GS, Hopewell S, et al. Feasibility of Surgical
779 Randomised Controlled Trials with a Placebo Arm: A Systematic Review. *BMJ*
780 *Open*. 2016;6(3):e010194.

781 95. Yamaguchi K, Tetro AM, Blam O, Evanoff BA, Teefey SA, Middleton WD.
782 Natural history of asymptomatic rotator cuff tears: A longitudinal analysis of
783 asymptomatic tears detected sonographically. *J Shoulder Elb Surg*.
784 2001;10(3):199-203.

785 96. Yamamoto A, Takagishi K, Osawa T, et al. Prevalence and risk factors of a
786 rotator cuff tear in the general population. *J Shoulder Elb Surg*.
787 2010;19(1):116-120.

788 97. Zhang W, Robertson J, Jones a C, Dieppe P a, Doherty M. The placebo effect
789 and its determinants in osteoarthritis: meta-analysis of randomised controlled
790 trials. *Ann Rheum Dis*. 2008;67(12):1716-1723. doi:10.1136/ard.2008.092015.

791 98. Zhang Z, Gu B, Zhu W, Zhu L, Li Q. Arthroscopic versus mini-open rotator cuff
792 repair: a prospective, randomized study with 24-month follow-up. *Eur J Orthop*
793 *Surg Traumatol*. 2014;24(6):845-850.

794 99. Zumstein MA, Rumian A, Lesbats V, Schaer M, Boileau P. Increased
795 vascularization during early healing after biologic augmentation in repair of
796 chronic rotator cuff tears using autologous leukocyte- and platelet-rich fibrin (L-
797 PRF): a prospective randomized controlled pilot trial. *J Shoulder Elbow Surg*.
798 2014;23(1):3-12.

799

Table 1: Study Characteristics

Author	Year published	Comparison	Participants (n)	Male (n)	Female (n)	Age	Dominant side (n)	Non dominant side (n)
Abrams <i>et al.</i> ¹	2014	Repair vs. Repair & Acromioplasty	114	64 (56.1%)	50 (43.9%)	58.8		
Aydin <i>et al.</i> ⁵	2010	Single vs. Double Row Repair	68			58.0		
Barber <i>et al.</i> ⁹¹	2016	Single vs. Double Row Repair	40	24 (60.0%)	16 (40.0%)	56.0	33	7
Barber <i>et al.</i> ⁶	2012	Repair vs. Repair & Human Dermal Matrix	42	31 (73.8%)	11 (26.2%)	56.0		
Berth <i>et al.</i> ⁷	2010	Partial Repair vs. Debridement & Acromioplasty	42	31 (73.8%)	11 (26.2%)	63.4	29	13
Bidwai <i>et al.</i> ⁸	2016	Mini-Open Repair vs. Acromioplasty	33	26 (78.8%)	7 (21.1%)	67.7		
Bigoni <i>et al.</i> ⁹	2009	Side-to-Side Repair vs. Tendon-to-Bone Fixation	50			59.0		
Boehm <i>et al.</i> ¹²	2005	Mason-Allen Suture vs. Kessler Suture	100	68 (68.0%)	32 (32.0%)	56.5		
Bryant <i>et al.</i> ¹⁴	2016	Repair & Porcine Small Intestine Mucosa vs. Repair	62	51 (81.3%)	11 (17.7%)	56.6		
Burks <i>et al.</i> ¹⁵	2009	Single vs. Double Row Repair	40			56.5		
Carbonel <i>et al.</i> ¹⁶	2012	Single vs. Double Row Repair	160	68 (43.5%)	92 (57.5%)	55.5		
Castricini <i>et</i>	2011	Repair & Platelet Rich Plasma	88	40	48	55.3		

<i>al.</i> ¹⁸		vs. Repair		(45.5%)	(55.5%)			
Cuff et al. ²¹	2012	Early Physiotherapy vs. Late Physiotherapy	68	38	30	63.2		
Dezaly et al. ²²	2011	Repair & Acromioplasty vs. Acromioplasty	127	58	69	67.8		
Duzgun et al. ²³	2011	Early Rehabilitation vs. Late Rehabilitation	29	3	26	56.3		
Flurin et al. ²⁸	2013	Repair vs. Repair & Acromioplasty	154	60	94	74.3		
Franceschi et al. ²⁹	2007	Single vs. Double Row Repair	60					
Gartsman et al. ³⁰	2004	Repair & Acromioplasty vs. Repair	93	42	51	59.7		
Gialanella et al. ³²	2011	Steroid Injection vs. Steroid injection vs. No Treatment (Control)	60	5	55	78.7		
Grasso et al. ³³	2009	Single vs. Double Row Repair	80	34	46	56.8	56	24
Greiner et al. ³⁵	2015	Lateralised Reverse Shoulder Arthroplasty vs. Reverse Shoulder Arthroplasty	34	12	22	75.4		
Gumina et al. ³⁶	2012	Repair & Platelet/Leucocyte Membrane vs. Single Row Repair	80	41	39	61.0	58	22
Jacquot et al. ⁴²	2014	Arthroplasty & Tenotomy vs. Arthroplasty, Tenotomy & Tendon Suture	103	50	53	68.0	75	28
Jo et al. ⁴³	2013	Repair & Platelet Rich Plasma	48	24	24	63.1	42	6

Jo et al. ⁴⁴	2015	vs. Repair Repair & Platelet Rich Plasma	74	(50.0%) 17	(50.0%) 57	60.4	57	17
Keener et al. ⁴⁶	2014	vs. Repair Repair & Traditional Rehabilitation vs. Repair & Immobilisation	124	(30.0%)	(77.0%)			
Kim et al. ⁴⁷	2011	Distal Clavicle Resection vs. Repair	83	40 (48.5%)	43 (42.5%)	56.9		
Kim et al. ⁴⁸	2012	Repair & Extracorporeal Shockwave Therapy vs. Repair	71	32 (45.1%)	39 (54.9%)	59.0	40	31
Kim et al. ⁴⁹	2012	Early Passive Motion vs. Immobilisation	105	44 (41.9%)	61 (58.1%)	60.0	69	36
Kim et al. ⁵⁰	2016	En Masse Repair vs. Double Layer Repair	82	27 (32.9%)	55 (67.0%)	65.3		
Ko et al. ⁸⁷	2008	Modified Mattress Suture vs. Simple Stitch	78			53.2		
Koh et al. ⁵³	2014	Repair & Four Weeks Immobilisation vs. Repair & Eight Weeks Immobilisation	100					
Krischak et al. ⁵⁴	2013	Occupational Therapy vs. Home Based Therapy	38	24 (63.2%)	14 (36.8%)	55.0	24	14
Kukkonen et al. ⁵⁵	2015	Physiotherapy vs. Acromioplasty & Physiotherapy vs. Repair, Acromioplasty & Physiotherapy	167	80 (47.9%)	87 (52.1%)	65.0	111	56
Lambers et al. ⁵⁷	2015	Repair vs. Physiotherapy	56	35 (62.5%)	21 (37.5%)	60.6	46	10
Lapner et al.	2012	Single vs. Double Row Repair	90	64	26	56.8	66	24

58					(71.1%)	(28.9%)			
Ma et al. ⁵⁹	2012	Single vs. Double Row Repair	53	29	24	61.2	34	19	
				(54.7%)	(45.3%)				
MacDonald et al. ⁶⁰	2011	Repair vs. Repair & Acromioplasty	86	56	30	56.8			
				(65.1%)	(34.9%)				
Malavolta et al. ⁶²	2014	Repair & Platelet Rich Plasma vs. Repair	54	17	37	54.6	42	12	
				(31.5%)	(68.5%)				
Merolla et al. ⁶³	2015	Repair & Tendisulfar vs. Repair	100	55	45	54.3	82	18	
				(55.0%)	(45.0%)				
Milano et al. ⁶⁴	2010	Metal Anchors vs. Biodegradable Anchors	110	66	44	61.6	70	40	
				(60.0%)	(40.0%)				
Milano et al. ⁶⁵	2013	Repair & Microfracture vs. Repair	73	41	32	61.8	54	19	
				(51.2%)	(43.8%)				
Mohtadi et al. ⁶⁸	2008	Mini-open Repair vs. Open Repair	63	42	21	56.6	55	8	
				(66.7%)	(33.3%)				
Moosmayer et al. ⁶⁹	2014	Repair vs. Physiotherapy	103	73	30	60.0	64	39	
				(70.9%)	(29.1%)				
Osti et al. ⁷⁶	2015	Repair & Electromagnetic Fields vs. Repair	66			62.0			
Osti et al. ⁷⁵	2013	Repair & Microfracture vs. Repair	57						
Pandey et al. ⁷⁸	2016	Repair & Platelet Rich Plasma vs. Repair	102	74	28	54.0	65	37	
				(72.5%)	(27.5%)				
Randelli et al. ⁸¹	2013	Repair & Platelet Rich Plasma vs. Repair	53	21	32	60.0	41	12	
				(39.6%)	(43.8%)				
Rodeo et al. ⁸⁴	2012	Repair & Platelet Rich Plasma vs. Repair	79	44	35	58.0			
				(55.7%)	(44.3%)				
Ruiz-Moneo	2013	Repair & Platelet Related	69	25	44	55.5			

et al. ⁸⁵		Growth Factor vs. Repair		(36.2%)	(63.8%)			
Shibata et al. ⁸⁸	2001	Sodium Hyaluronate Injection vs. Steroid Injection	78	55	23	61.5	50	28
Shin et al. ⁸⁹	2012	Repair & Acromioplasty vs. Repair	120	67	53	56.8	87	33
van der Zwaal et al. ⁷⁷	2013	Arthroscopic Repair vs. Mini – Open Repair	95	57	38	57.6	72	23
Wang et al. ⁹³	2015	Single vs. Double Row Repair	248	67	95	58.0	79	88
Zhang et al. ⁹⁸	2014	Mini-Open Repair vs. Arthroscopic Repair	108	55	53	54.1	84	24
Zumstein et al. ⁹⁹	2015	Repair & Platelet Rich Plasma vs. Repair	20	10	10	63.9	18	2

